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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,531	02/21/2002	Denis Martin	484112.423	3055

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EXAMINER	
DUFFY, PATRICIA ANN	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/078,531	MARTIN ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17,19-38 and 40-53* is/are pending in the application.

4a) Of the above claim(s) *22-29 and 31-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,19-21,30,35,37,38 and 41-53* is/are rejected.

7)☒ Claim(s) *40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ESPONSE TO AMENDMENT

The amendment and response filed 4-14-06 has been entered into the record. Claims 1-16, 18, 36 and 39 have been cancelled. Claims 17, 19-35, 37-38 and 40-53 are pending. Claims 17, 19-21, 35, 37-38 and 40-53 are under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Election/Restrictions

This application contains claims 22-29, 31-34 are drawn to an invention nonelected with traverse in the response of 2-27-04. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Rejections Withdrawn

The rejection of claims 17, 18, 21, 30, 35-40, 42-45 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

Rejections Maintained

Specification

The use of the trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Applicants must correct this issue.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Failure to correct this in the next office action will be ***considered non-responsive on this issue for the second time and this case will be abandoned.***

Double Patenting

Claims 17-21 and 30 of this application conflict with claims 18-20, 22 and 35-38 of Application No.10/476,614 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Applicants have neither cancelled the claims from the conflicting application nor addressed this issue. ***Applicants are also non-responsive on this issue.***

Claims 17, 19-21 stand provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 17-21 and 30 of copending Application No. 10/476,614. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Applicants are claiming the same structures.

It is noted that Applicants have lumped the traversal of three different 112, 1st paragraph rejections together. As such, it is difficult to separate the response to teh disparte issues. Applicants are directed to separate their arguments to address the specific concerns under each separate rejection so proper consideration of the response can be made. Despite the confusion of the record, an attempt was made to addresses the traversal of the lumped issues.

Claims 17, 19-21, 35, 37-38 and 40-53 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons made of record in the Office Action mailed 10-14-05.

Applicants' arguments have been carefully considered but are not persuasive. Applicants point to the specification by page and line number. At each of these occurrences, the polypeptide fragment or analogue has generate antibodies that bind SEQ ID NO:2. In the instant case the recitation of "BVH-P7 of *S. pyogenes*" does not define any particular structure to which the antibody has to bind. Further, the BVH-P7 specific antibodies referenced at page 33, lines 15-18 is in fact SEQ ID NO:2 as clearly shown at page 29 example 4. The argued asserted support for the limitation that the variant elicits antibodies specific for SEQ IDNO:2 of *S. pyogenes* as set forth in the specification is not present in the claims.

Claims 17, 19-21, 35, 37-38 and 40-53 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons made of record in the Office Action mailed 10-14-05.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that the specification describes 10 different homologues of the BVH-P7 gene. This is not persuasive, the 10 different homologues all fall in the range of 95% identical. Therefore, the described homologues do not support the claims to 90, 80 or 70% homologues as argued. Applicants have not described the genus that has this degree of variability. Applicants have not described the breadth of the claimed invention.

Applicants argue that the sequence itself is an express disclosure of all the fragments within it. This is in not persuasive, the claims are drawn to epitopes or fragments with particular function not mere fragments. The specification does not describe 70% identical polypeptides or fragments of 10 consecutive nucleotides thereof that generate antibodies to a protein with unknown structure. Applicants have simply not described any polypeptide whose sole characteristic is 10 consecutive amino acids in common with SEQ ID NO:2 or any % identical variant thereof. The issue is not could one make the variants, but rather did Applicants describe the genus of variants. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). It is clear from the alignment of the homologs referenced by Applicants that they had described the genus of 95% identical variants and consisting of fragments. However, the homologs when aligned do not demonstrate description of a genus of polypeptides that are 70, 80 or 90% identical, or a genus of polypeptides comprising at least 10 consecutive amino acids thereof. Applicants' have no written description for any of these other desirable compounds are not enabled for such and that applicants' are not entitled for dominance of further patentable inventions by claims that are insufficiently supported by the specification (*In re Fisher*, 166 USPQ 18, CCPA (1970)).

Claims 17, 19-21, 35, 37-38 and 40-53 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated polypeptide from *S. pyogenes* having at least 95% identity to the full-length amino acid sequence as set forth in SEQ ID NO:2, an isolated polypeptide comprising the amino acid sequence as set forth in SEQ ID NO:2 lacking the leader sequence consisting of amino acid residues 1 to 21 of

SEQ ID NO:2 or an isolated polypeptide of SEQ ID NO:2 wherein the N-terminal methionine residues is deleted and pharmaceutical compositions comprising an isolated polypeptide of SEQ ID NO:2 lacking the leader sequence consisting of amino acid residues 1 to 21 of SEQ ID NO:2 or an isolated polypeptide comprising the amino acid sequence as set forth in SEQ ID NO:2 wherein the N-terminal methionine residues is deleted, it does not reasonably provide enablement for polypeptides comprising 10 contiguous amino acids, chimerics, multimers or epitopes or at least 70%, 90% variants, and non-natural variants of polypeptides that are at least 95% identical with a fragment or the full length of SEQ ID NO:2, chimerics or multimers thereof for reasons made of record in the Office Action mailed 10-14-05.

Applicants' arguments have been carefully considered but are not persuasive. Applicants provide limited arguments. Applicants argue description of homologues. This is not persuasive, the description of homologues is limited to 95% variants. Applicants merely assert that fragments and epitopes can be made and tested for specificity, no specific epitopes have been described. Applicants argue that the art provided in the office action is not on point because no particular structures were described. This is not persuasive, the fact pattern of the case law is the same. The polypeptide is narrowly disclosed and broadly claimed. Applicants are essentially broadly claiming any polypeptide having a sub-sequence in common that generate an antibody that binds *S. pyogenes*. This is even broader than the fact scenario than presented in *Amgen Inc.. v. Chugai Pharmaceutical Co.*, 18 USPQ2d 1016, 1026 (CAFC 1991). Applicants' have no written description for any of these other desirable compounds are not enabled for such and that applicants' are not entitled for dominance of further patentable inventions by claims that are insufficiently supported by the specification (*In re Fisher*, 166 USPQ 18, CCPA (1970)). The courts have held ".. in cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provide broad enablement in the sense that

once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws; in cases involving unpredictable factors, such as most chemical reactions and physiological activity, scope of enablement varies inversely with degree of unpredictably of factors involved." (*In re Fisher* 166 USPQ 18 (CCPA)). Applicants again argue that any fragment is essentially described by virtue of its sequence description. This is not persuasive, Applicants are not limited to fragments of disclosed sequences, but encompass any polypeptide with that sequence buried within it. Applicants arguments are no commensurate in scope with their claims. Further, it specifically encompasses fragments of non-disclosed non-enabled % identical variants. Applicants have not enabled these polypeptides. Applicants argue make and test for epitope and make and test for vaccines. This is not persuasive for all the reasons previously made of record. The record is absolutely clear that antibody production is not equivalent to protection from infection as is requisite for a pharmaceutical compositions/vaccine. The pharmaceutical compositions envisioned by this specification are limited to vaccines. As such, the claims are not enabled for such. The courts have held that the disclosure is insufficient when testing is necessary to determine the actual use or possible lack of use *(In re Kirk and Petrow* 153 USPQ 48 (CCPA 1967) and the examiner has appropriately cited evidence which is reason to doubt the objective truth of the statements contained in applicants specification. (*In re Marzocchi and Horton*, 169 USPQ 367 (CCPA 1971)).

Claims 17, 19, 35 and 36 are rejected under 35 U.S.C. 102(b) as anticipated by Dixon et al, PIR_79 Database Accession Number T51594, Dixon et al, August 18, 2000 is maintained for reasons made of record.

Applicants' arguments have been carefully considered but are not persuasive. The claims recite open language and not "consisting of", therefore the polypeptides of the prior art comprise the claimed fragments. Applicants also argue priority of the

application to the provisional application. This is not persuasive because the provisional document lacks written description for reasons made of record.

Claims 17, 19, 35 and 36 are rejected under 35 U.S.C. 102(b) as anticipated by McDonald on et al, PIR_79 Database Accession Number JE0176, July 03, 1998 s maintained for reasons made of record.

Applicants' arguments have been carefully considered but are not persuasive. The claims recite open language and not "consisting of", therefore the polypeptides of the prior art comprise the claimed fragments. Applicants also argue priority of the application to the provisional application. This is not persuasive because the provisional document lacks written description for reasons made of record.

Claims 17, 19, 35-38, 40-45 are rejected under 35 U.S.C. 102(a) as being anticipated by Ferretti et al (PNAS, 98(8):4658-4663, April 10, 2001) s maintained for reasons made of record.

Applicants' arguments have been carefully considered but are not persuasive. The claims recite open language and not "consisting of", therefore the polypeptides of the prior art comprise the claimed fragments. Applicants also argue priority of the application to the provisional application. This is not persuasive because the provisional document lacks written description for reasons made of record.

Claims 17, 19, 20, 21, 30, 35-38, 41, 42 and 43 are rejected under 35 U.S.C. 102(a) as being anticipated by Le Page et al (WO 01/32882, published May 19, 2001) s maintained for reasons made of record.

Applicants' arguments have been carefully considered but are not persuasive. The claims recite open language and not "consisting of", therefore the polypeptides of the prior art comprise the claimed fragments. Applicants also argue priority of the application

to the provisional application. This is not persuasive because the provisional document lacks written description for reasons made of record.

Allowable Subject Material

The examiner suggests the following specific claim language to place the 95% variants in condition for allowance:

Claim A. An isolated polypeptide comprising at least 95% amino acid sequence identity along its entire length to the complete polypeptide amino acid sequence set forth in SEQ ID NO:2, wherein the polypeptide elicits an immune response specific for *Streptococcus pyogenes*..

Claim A1. The isolated polypeptide of claim A, wherein the polypeptide comprises the amino acid set forth in SEQ ID NO:2.

Claim B. An isolated peptide fragment consisting of at least 10 contiguous amino acids of the polypeptide of claim A or A1.

Claim C. A pharmaceutical composition comprising the polypeptide of claim A or A1 and a pharmaceutically acceptable carrier, diluent or adjuvant.

Status of Claims

All examined claims stand rejected. Claim 40 is objected to as depending from a rejected base claim.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can generally be reached on M-Th 6:30 am - 6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patricia A. Duffy

Primary Examiner

Art Unit 1645